UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION *This Document Relates to All Cases*	Case No. 13-md-2452-AJB-MDD **JOINT SUBMISSION REGARDING PROTECTIVE ORDER**

Pursuant to the Court's November 19, 2013 Order Regarding Discovery Disputes Identified in Joint Submission Filed November 18, 2013 (Doc. No. 192), undersigned counsel for the Plaintiffs, together with undersigned counsel for Defendants Amylin Pharmaceuticals, LLC ("Amylin"), Eli Lilly and Company ("Lilly"), Merck Sharp & Dohme Corp., and Novo Nordisk Inc., (collectively, the "Parties") ask the Court to resolve outstanding disputes related to the Protective Order.

PLAINTIFFS' POSITION:

1. Brief Summary of Issues Presented to the Court:

Plaintiffs request the Court make three modifications to the Protective Order (the "Order") entered in the *Moses Scott* case[1]:

(1) Revise Paragraph 9 to account for situations where a non-party witness appears at a deposition (e.g., a prescribing physician, a government employee, or a scientific researcher not retained as an expert) and refuses to execute the endorsement to the Order. Such a refusal would preclude the Parties from utilizing material evidence, documents, and information in developing their case because the Order requires a signed endorsement prior to sharing Confidential materials with a deponent. For example, if a prescribing physician – many of whom have financial ties to the defendants – refused to sign an endorsement to the Order, then Plaintiffs would not be able to question the prescribing physician on whether information[2] in the Defendants' possession, but not disclosed to the physician, would have altered their decision to prescribe the medication. This, in turn, will severely prejudice discovery relating to Defendants' learned intermediary defense.

(2) Revise Paragraph 5(d) to account for situations where one or more defense counsel (or client representatives) attend a deposition involving another of the MDL defendants (i.e., every joint use[3] case). As written, in such situations, 5(d) requires a minimum fourteen days notice of a Party's intent to disclose Confidential materials at the deposition of all parties, experts, and non-party witnesses who are a "Customer or

[1] Defendants argue as if there is an existing Protective Order in this MDL. There is not. Rather, before this MDL was created, an Order was agreed to in the *Scott et al.* case, 12-cv-2549, which case involved only a fraction of the Plaintiffs here, did not involve all attorneys eventually appointed to the Plaintiffs' Steering Committee, and did not involve all Defendants here.

[2] Examples of information Plaintiffs would be unable to show a prescriber could include: (1) call notes from meetings with defendant sales representatives; (2) unpublished studies or data suggesting an altered safety profile; (3) statistical analyses performed by defendants impacting published studies, and similar materials and information.

[3] Joint use cases, where a Plaintiff took more than one Incretin-based drug, are numerous in MDL 2452, and while the exact number is not known, Plaintiffs agree with Counsel for Merck who argued to the JPML that, "[…] the fact is that 40 percent of the cases do involve more than one of the -- the drugs before this Panel."

Competitor (or an employee of either)" of the Producing Party. The Defendants in this MDL are all competitors, and as such, 5(d) would require Parties to identify deposition exhibits marked Confidential at least fourteen days prior to said deposition – which would be extremely onerous[4], likely require repeated briefing, impede use of newly discovered documents, and invade the attorney work-product privilege. Paragraph 5(d) should be amended to remove the prior disclosure requirement in depositions.

(3) Revise Paragraph 8(c) to account for situations where a Party seeks to declassify documents designated as confidential by the Producing Party. As written, 8(c) could be read to improperly shift the burden to the Party disputing the Confidential designation. The paragraph should be amended as shown in Exhibit A to clearly place the burden on the party seeking confidentiality to demonstrate that such designation is proper.

2. The *Moses* Order, If Entered Here, Could Restrict Fair Use of Evidence in Depositions:

Paragraph 9 requires Counsel obtain a signed Endorsement prior to disclosing Confidential materials to any non-party deponent, including prescribing physicians, unless Counsel obtains written consent or a Court order allowing disclosure.[5] The court should modify Paragraph 9, as shown in Exhibit A, to make the Order binding on non-party deponents subject to the Court's jurisdiction by subpoena or who otherwise consent to jurisdiction by voluntarily appearing at deposition. Such a modification would allow the Parties to use Confidential materials in non-party depositions irrespective of a deponent's willingness to sign the endorsement.

[4] After a review of metadata produced by Eli Lilly and Amylin, not visually confirmed on each page produced, but confirmed by viewing a representative sampling, Plaintiffs have grave concerns related to abuse of the Order as Amylin labeled 3,786,600 out of 4,279,101 pages (or 88.5%) as either confidential or eyes only, and Eli Lilly labeled 2,135,342 out of 2,159,567 pages (or 98.9%) as either confidential or eyes only.

[5] Case No. 12-CV-2549-AJB (MDD), Doc. 32, Paragraphs 9(a) and 5.

Plaintiffs proposed paragraph 9(b) is curative as it binds deponents and their counsel to the Order so long as they are provided a copy of the Order and advised on the record that they must abide by the terms of the Order as if they had executed the endorsement. This admonishment would permit the showing of Confidential materials to non-party deponents for purposes of examination, and allows the Court to enforce the Order.

The Court can acquire jurisdiction over virtually any non-party by way of subpoena or that non-party's voluntary appearance at deposition,[6] and Rule 45 empowers Courts to hold them in contempt for refusing to obey related orders.[7] Per the Supreme Court, "it is firmly established that '[t]he power to punish for contempts is inherent in all courts.'"[8] There is no doubt the Court can enforce its lawful orders against non-party deponents subject to the Court's jurisdiction irrespective of consent to those orders – just as the Second Circuit affirmed three years ago, at the urging of Defendant Lilly.[9]

3. The *Moses* Order, If Entered Here, Would Invade Privilege by Requiring Prior Notice of Exhibits:

Paragraph 5(d) requires a minimum fourteen days notice before a Party can disclose Confidential materials at depositions of a customer or competitor of the Producing Party. Since Defendants in this MDL are all competitors, 5(d) requires fourteen days notice of all potential deposition exhibits in, at least, joint use cases. This requirement would be extremely onerous, preclude use of new documents, allow

[6] Fed. R. Civ. P. 30 ("A party may […] depose any person […]. The deponent's attendance may be compelled by subpoena under Rule 45.")

[7] Fed. R. Civ. P. 45 (g) & Practice Commentaries (""A subpoena, like a summons, is a jurisdiction-getting paper.")

[8] *Chambers v. Nasco, 501 U.S.* 32, 44 (1991) (internal citations omitted).

[9] "If courts cannot bind third parties who aid and abet the violation of their protective orders, then any party, agent, attorney or expert who comes into possession of material he wanted to use against the producing party could simply disseminate the information quickly, then deal with the damages issue after the fact." *Eli Lilly & Co. v. Gottstein*, 617 F.3d 186, 195 (2d Cir. 2010)(affirming trial court order enjoining non-party from releasing confidential documents).

for unfair coaching and preparation of witnesses[10], and would violate the work product privilege.

By necessity, a compilation of exhibits reflects a lawyer's mental impressions and processes. Therefore, counsel's compilation and selection of exhibits – which necessarily was done by counsel – is protected under the work product privilege. The purpose of the qualified privilege for attorney work product, which is codified in Federal Rule of Civil Procedure 26(b)(3), is to establish a zone of privacy in which lawyers can analyze and prepare their client's case free from scrutiny or interference by an adversary.[11]

Paragraph 5(d) should be amended to remove the prior disclosure requirement for depositions to avoid these issues, and to plainly satisfy any Defendants' concerns, Plaintiffs' propose the Court add language stating defendants will not use each other's confidential materials for any purpose whatsoever, other than as necessary for litigation. To the extent a Defendant here has a genuine concern at a deposition regarding a document that cannot be shared even in light of the Order, Defendants retain the right under the agreed-upon portions of the Deposition Protocol to move for a protective order at that time.[12] These modifications will protect privilege, the integrity of truth-seeking process, and confidentiality.

4. <u>The *Moses* Order Arguably Misplaces The Burden Regarding Confidentiality Designations</u>:

Paragraph 8(c) can be read to improperly shift the burden to the Party disputing a Confidential designation – a process apparently being abused by Defendants[13]. The Order entered by the Court in this case is generally called an 'Umbrella Order.' The

[10] Disclosing the mental impressions of counsel before a deposition to allow Defendants to prepare their witnesses with their "story" based upon each of the disclosed exhibits would impede the truth-seeking function of discovery. See, e.g., *Perry v. Leake*, 488 U.S. 272, 282 & n.4 (1989) (noting that witness coaching by conferral with counsel between direct examination and cross examination can impede the truth-seeking function at trial).

[11] *Hobley v. Burge*, 433 F.3d 946, 949 (7th Cir. 2006).

[12] See see ECF 222-1, p. 8–9, § J ("Disputes During Depositions).

[13] *See* Footnote 3 *supra*.

Manual for Complex Litigation ("MCL") states, "Umbrella orders provide that all assertedly confidential material disclosed […] is presumptively protected unless challenged. Such orders typically are made without a particularized showing to support the claim for protection, but such a showing must be made whenever a claim under an order is challenged."[14] Indeed, in citing to the *Cipollone* case, the MCL further notes, "Umbrella orders do not eliminate the burden on the person seeking protection of justifying the relief sought as to every item, but simply facilitate rulings on disputed claims of confidentiality."[15]

In light of the clear guidelines discussed above, paragraph 8(c), as shown in Exhibit A, would plainly and properly place the burden on the party seeking confidentiality to demonstrate that such designation is proper once the disputing Party identifies the documents subject to contest.

In conclusion, Plaintiffs respectfully request the Court adopt the revised Order, attached hereto as Exhibit A, to address the three issues outlined herein.

[14] Manual for Complex Litigation, Fourth, Section 11.432 (emphasis added).
[15] *Id.*; Citing to *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1122 (3d Cir. 1986).

DEFENDANTS' POSITION:

The Parties vigorously negotiated, offered and accepted compromises, reached final agreement upon terms, and asked for the Court's final approval of the stipulated Protective Order more than five months ago. *See* Doc. No. 192. Contrary to plaintiffs' suggestion in footnote 1, the very same group of defendants and lead plaintiffs' counsel submitting this joint brief were involved in those negotiations. Now, perhaps feeling as though they have nothing to lose, plaintiffs' counsel are asking the Court to rewrite the agreement—an agreement that Defendants already have relied upon in collecting, reviewing, and producing documents—by altering key provisions that go the core of the Protective Order's purpose, including Defendants' ability to protect Confidential information from being made public or, no less important, made available to competitors.[16] Protecting a party's Confidential information is important in any litigation of this scope and nature, but it is particularly crucial here, where Lilly, Amylin, Merck, and Novo Nordisk are not just codefendants, they are also competitors.

The Court should deny each of Plaintiffs' requests.

I. The Protective Order Appropriately Limits the Distribution of Confidential Information to Those Willing to Protect It.

Plaintiffs seek to remove the requirement that a non-party deponent sign an Endorsement to the Order before they are shown Confidential Discovery Materials. But non-party witnesses who expressly refuse to endorse and abide by the terms of the Protective Order are exactly the individuals who should *not* be receiving Confidential documents.

[16] Defendants have, at plaintiffs' request, agreed to update the stipulated Protective Order to reflect the formation of this MDL and to make other minor clarifications. Those changes are incorporated into Exhibit A, and are not reflected in the "redlines." The "redlines" in Joint Exhibit A reflect only the proposed revisions that are the subject of dispute.

Under the June 3, 2013 stipulated Protective Order, non-party deponents must agree to abide by the terms of the Protective Order before they can be shown Confidential documents. As parties and judges in other litigations have determined,[17] this approach makes sense because a non-party witness who expresses an unwillingness to protect Confidential material, naturally is less likely to do so.

Significantly, plaintiffs offer no reason to believe that the Court legally could bind unwilling non-parties to the Protective Order absent their consent. Plaintiffs cite only the Court's broad subpoena and contempt power, resting on the truism that "the Court can enforce its lawful orders against non-party deponents." *See supra* at 4. Courts have lawful authority to require an unwilling non-party to attend a deposition and answer questions, of course, but that does not answer whether non-parties unwillingly can be bound to confidentiality provisions controlling what they can and cannot discuss with the media or others *after* the compulsory examination ends.[18] In effect, plaintiffs have asked the Court to revise the stipulated Protective Order in this manner based solely on plaintiffs' prediction that their proposal will withstand future legal challenge, unencumbered by any authority that this is the case.

Plaintiffs focus on one example of non-party deponents to whom they wish to show Confidential documents, even if the witness refuses to endorse the Protective Order—plaintiffs' healthcare providers. But plaintiffs' healthcare providers are fact witnesses, who properly should be testifying about plaintiffs' medical conditions and

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[17] Notably, the *Prempro Products Liability Litigation* in the Eastern District of Arkansas adopted the same system set out in the Court's Order. *See* Ex. A, ¶¶ II.D.1, II.E.

[18] Plaintiffs' citation to *Gottstein*, supra at 4, n. 9, is misplaced. The very basis of the injunction against dissemination of confidential documents was the fact that the non-party witness—Dr. Egilman, a plaintiffs' expert—***had endorsed the protective order***. Moreover, the defendant Gottstein voluntarily appeared and subjected himself to the jurisdiction of the Court. *In re Zyprexa et al., In re Injunction*, 474 F. Supp. 2d 385, 428 (E.D.N.Y. 2007). The Second Circuit held that jurisdiction was proper because Gottstein had aided and abetted Dr. Egilman's disclosure of confidential documents. *Gottstein*, 617 F.3d at 194–195 (2d Cir. 2010).

treatment, not addressing internal company documents that they have never seen before. In other words, plaintiffs' want the ability to use Confidential documents in this manner *not* to facilitate an appropriate examination of plaintiffs' healthcare providers. To the contrary, they wish improperly to prejudice that testimony on issues of general causation and corporate "state of mind."

Plaintiffs' go even further than eliminating the requirement that non-party witnesses agree to abide by the Protective Order before gaining access to Confidential material. Under plaintiffs' proposal, counsel could simply provide a copy of the Order, instruct the witness as to its applicability, and proceed to show the non-party witness whatever Confidential documents counsel desired to show. If plaintiffs' revision were adopted, this would be true even if the witness *expressly* refused to acknowledge, sign, or abide by the terms of the Protective Order, or even affirmatively announced an intention *not* to abide by the Order's provisions.

Finally, plaintiffs' proposed change is particularly ill-founded given that the Protective Order already provides a reasonable alternative to the relief plaintiffs seek. The Protective Order allows counsel—on a case-by-case basis, when and if the problem arises and based on the factual circumstances of that particular case—to seek authorization to use Confidential information where the deponent refuses to sign the Endorsement. *See* Or. ¶ 5(c); see also *See Brown Bag Software v. Symantec Corp.*, 960 F. 2d 1465, 1471 (9th Cir. 1992) (requiring that courts evaluate confidentiality issues in light of the "specific factual circumstances" of each case). Plaintiffs proposed change is neither necessary nor appropriate.

II. The Ability to Show Defendants' Confidential Documents to Competitors Without Notice Would Fundamentally Undermine the Protective Order's Purpose.

Plaintiffs' request to exempt depositions from Paragraph 5(d)'s notice requirement fundamentally undermines the purpose of the Protective Order. The Defendants in this case are direct business competitors—not just in the rapidly

evolving and highly innovative area of type 2 diabetes treatments, but generally in the development of pharmaceutical medications. So adequately protecting the Defendants' Confidential information is keenly important. In this case, ensuring that the Order serves to protect the Defendants' Confidential information is essential to facilitating Defendants' discovery obligations to plaintiffs. *See Brown Bag Software*, 960 F.2d at 1470. Responsive documents will include sensitive material about marketing and scientific initiatives, among other Confidential information, the disclosure of which could cause Defendants material competitive harm.

Plaintiffs' proposed modification to Paragraph 5(d) would give plaintiffs' counsel *carte blanche* to show any Confidential Discovery Materials, no matter how sensitive, to any customer or employee of any competitor at a deposition, without providing the producing party an opportunity to object and seek the Court's protection in advance. Plaintiffs suggest that the problem is solved simply by adding language to the Protective Order requiring that the Confidential information not be used for non-litigation purposes.[19] Courts have recognized, however, that ordering competitors to use sensitive confidential information only for litigation purposes is impractical and have routinely prohibited competitor employees from receiving confidential materials, even if purportedly just for purposes of litigation. *See id.* at 1470–72 (prohibiting in-house counsel from reviewing confidential materials); *Markey v. Verimatrix, Inc.*, 2009 WL 1971605, at *2–3 (S.D. Cal. July 8, 2009) (Battaglia, J.) (same).

Plaintiffs' concerns about tipping their hand by showing documents in advance of depositions are unfounded. Plaintiffs' will not be required to disclose a Defendant's Confidential documents in advance of examining an employee of *that same Defendant*. The disclosure obligation only arises if plaintiffs' counsel wish to

[19] Plaintiffs also suggest that this Court field telephone calls whenever this issue arises. *See supra* at 5, n. 12. At best, this effectively asks the Court to "kick the can down the road," not to mention placing an unnecessary burden on both the Court and the parties.

use Confidential documents of one Defendant to examine the employee of a *different Defendant* or other parties listed in paragraphs 5(a)(1) or 5(a)(6)–(8).[20]

III. The Protective Order Does Not, and Need Not, Assign in Advance the Burden for Deciding Confidentiality Disputes.

Plaintiffs' suggested revision to Paragraph 8(c) is inappropriate and unnecessary. Paragraph 8(c) does not address the burden for challenging a confidentiality designation, and Plaintiffs' fail to identify what language is potentially objectionable. The language in the Order is in all material respects the same as Paragraph 18 of this District's Model Protective Order, which also (1) allows confidentiality designations to remain in place unless successfully challenged and (2) does not allocate the burdens in evaluating such a challenge. This Court is perfectly capable of applying the appropriate legal standards for resolving confidentiality disputes upon briefing by the Parties, based on whatever facts are at hand. Where the burden should appropriately lie may well vary under the particular circumstances. There is no need for the Protective Order to allocate burdens in advance of any tangible dispute.

Respectfully submitted:

Dated: December 19, 2013

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[20] The Protective Order allows a producing party's Confidential Materials to be disclosed to other Defendants' outside counsel. Plaintiffs' statement that the notice requirement applies to "all potential deposition exhibits in, at least, joint use cases" is incorrect.

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SIGNATURE ATTESTATION

Pursuant to Section 2.f.4 of the Court's CM/ECF Administrative Policies, I hereby certify that authorization for the filing of this document has been obtained from each of the other signatories shown above and that all signatories have authorized placement of their electronic signature on this document.

s/ Vickie E. Turner
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